DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

'99 MAY -7 P3:42

MAY - 5 1999

Re: Omnicef® Tablets
Docket No.: 98E-0754

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,559,334, filed by Warner-Lambert Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Omnicef® Tablets, the human drug product claimed by the patent.

The total length of the regulatory review period for Omnicef® Tablets is 2,745 days. Of this time, 2,288 days occurred during the testing phase and 457 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 1, 1990.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on June 1, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 4, 1996.

   FDA has verified the applicant's claim that the new drug application (NDA) for Omnicef® Tablets (NDA 50-739) was initially submitted on September 4, 1996.

3. The date the application was approved: December 4, 1997.

   FDA has verified the applicant's claim that NDA 50-739 was approved on December 4, 1997.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Charles W. Ashbrook
Warner-Lambert Company
Parke-Davis Pharmaceutical
2800 Plymouth Road
Ann Arbor, MI 48105

DATE: MAY - 5 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Omnicef® Tablets
Docket No. 98E-0754, FRDTS# OC99123

Attached is a FR Notice for the human drug product, Omnicef® Tablets. This document has been internally reviewed and cleared by OHA.

Please note that Omnicef® Tablets is a registered trademark. Therefore, the superscript "R" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service
Food and Drug Administration

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# Memorandum

Date: MAY - 5 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for Omnicef® Tablets

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **98E-0754** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,559,334**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

98E-0754